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OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, L.L.P. 1940 DUKE STREET ALEXANDRIA, VA 22314			EXAMINER KASSA, TIGABU	
			ART UNIT	PAPER NUMBER
			1619	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/529,743	Applicant(s) SIMONNET, JEAN-THIERRY	
	Examiner TIGABU KASSA	Art Unit 1619	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 04 August 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-88 is/are pending in the application.
- 4a) Of the above claim(s) 41-52, 54-60, 81-82, and 86 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 61-66, 68-80, 84-85, and 87-88 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>08/04/09</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This Office Action is in response to the amendment filed August 04, 2009. **Claims 41-52, 54-66, 68-82, 84-88 are currently pending. Claims 61-66, 68-80, 84-85, and 87-88 are under consideration in the instant office action.** Claims 41-52, 54-60, 81-82, and 86 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claims. Claims 1-40, 53, 67, and 83 are cancelled. Applicant's amendment has necessitated a new ground of rejection.

Information Disclosure Statement

The information disclosure statement (IDSs) submitted on 08/04/09 is noted and the submissions are in compliance with the provisions of 37 CFR 1.97. Accordingly, the examiner has considered the references.

Withdrawn rejections:

Applicant's amendments and arguments filed on 08/04/09 are acknowledged and have been fully considered. All rejections applied in the previous office action are hereby withdrawn as a result of applicants claim amendments.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

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having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness

Claims 61-66, 68-73, 75-80, 84, and 87-88 are rejected under 35 U.S.C. 103(a) as being unpatentable over Seo et al. (WO 01/12718) in view of L'Alloret (US Patent No. 6994846).

Applicant Claims

Applicant claims a cosmetic composition comprising at least one aqueous phase, at least one lipophilic compound and at least one block amphiphilic copolymer, wherein the amphiphilic copolymer forms micelles on contact with water comprising at least one nonionic hydrophilic polymer block and at least one hydrophobic polymer block. Instant claim 62 recites in the

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composition the block amphiphilic copolymer is the sole solvent for the lipophilic compound.

Instant claim 63 requires in the composition the molecular weight of the block copolymer is between 1,000 and 100,000. Instant claim 64 in the composition the weight ratio of the ionic or nonionic hydrophilic polymer block to the hydrophobic polymer block is between 1/100 and 50/1. Instant claim 65 recites in the composition the weight concentration ratio between the lipophilic compound and the block copolymer is between 0.005 and 0.5. Instant claim 66 recites in the composition the hydrophobic polymer block comprises one or more polymerized monomer units from the list recited in the claim. Instant claim 68 recites in the composition the hydrophobic block copolymer is nonionic and selected from the list recited in instant claim 68. Instant claim 69 recites in the composition the amphiphilic copolymer comprises at least one nonionic hydrophilic polymer block one selected from the group consisting of polyethylene oxide and polyvinylpyrrolidone. Instant claim 70 recites in the composition the hydrophobic polymer block is selected from the list recited in the instant claim. Instant claim 71 recites in the composition the block amphiphilic copolymer is selected from the list recited in the instant claim. Instant claim 72 recites the incorporation of lipophilic compound from the list recited in the instant claim. Instant claim 73 recites the incorporation of lipophilic compound from the list recited in the instant claim. Instant claim 75 recites the incorporation of sunscreen from the list recited in the instant claim. Instant claim 76 recites the incorporation of 1,3,5-triazine derivative from the list recited in the instant claim. Instant claim 77 recites the composition further comprises butylmethoxydibenzoylmethane. Instant claim 78-79 recite the incorporation of lipophilic compound from the list recited in the instant claims. Instant claim 80 recites the incorporation of formulation adjuvant in the composition from the list recited in the instant

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claim. In additional further limitation instant claim 84 requires in the composition the weight concentration ratio between the lipophilic compound and the block copolymer is between 0.005 and 0.02. Instant claim 87 recites exactly the same limitations like instant claim 61 except that the limitation of the amphiphilic copolymer forms micelles on contact with water is not incorporated in instant claim 87. Instant claim 88 recites the composition of claim 87, wherein the solubility of the lipophilic compound in the aqueous phase of the composition is at least 15 times greater than the solubility of the lipophilic compound in water.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

Seo et al. teach a composition capable of forming a micelle in body fluids or in aqueous medium (see abstract). Seo et al. teach a composition comprising **a block copolymer containing a hydrophilic and a hydrophobic polymer block** (abstract). The composition comprises an amphiphilic block copolymer has a hydrophilic poly(alkylene glycol), which is a nonionic polymer and a hydrophobic biodegradable polymer component (abstract). The amphiphilic block copolymer as described through out the document does not comprise an ionic water-soluble polymer block. The amphiphilic polymer **solubilizes poorly water soluble drugs (i.e. lipophilic compounds) in aqueous media** (abstract). Preferred **hydrophobic polymer may be, e.g., polycaprolactone (page 6)**. Preferred molecular weights of polymers to be used for **oral, ophthalmic or external use are 1000-10000 (page 7)**. The hydrophilic portion of the block polymer is preferably 40-70% which the examiner calculates is a **1/1.5 to 2.3/1 ratio of hydrophilic to hydrophobic polymer blocks (page 6)**. The lipophilic compound is more preferably 5-30% by weight of the block copolymer which the examiner calculates is **a weight**

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ratio of 0.05-0.3 (page 4). Examples of lipophilic compounds included in the composition are **anti-inflammatory agents, antifungal agents, and sex hormones** (page 8). Specific examples include **aspirin, testosterone and progesterone** (page 8). **Organic solvents** may optionally be included in the composition (page 8). Seo et al. also teach that the organic solvent is an essential component in the composition (page 8). One can infer from this statement that the addition of the organic solvent is not an essential element for solubilizing rather the organic solvent may be added to facilitate better solubility of a drug and increase the loading efficiency into a micelle as described by Seo et al. rendering instant claims 62 and 87 obvious. Furthermore, the examiner also brings applicants attention to the illustrative examples listed on page 14, table 1, to the examples 1-3 wherein the composition does not contain at all any solvent but the block copolymer, hydrophilic polymer and the drug. In examples 1-3 the loading efficiency of 100% and the solubility of the drugs were also described in mg/mL concentration values (page 16, table 2). Additionally, with regard to instant claim 88 the examiner brings applicants attention to the loading efficiency and solubility table 2, wherein applicant used controls wherein the block copolymer is not added, for example, C1** the solubility concentration is 0.001 mg/mL whereas when the block copolymer is present, the concentration is 30 mg/mL, which is approximately 30 times higher, which addresses instant claim 88.

Ascertainment of the Difference Between Scope the Prior Art and the Claims

(MPEP §2141.012)

Seo et al. do not teach the specific hydrophobic polymers disclosed in instant claims 61, 66, 68 and 69, nor of the amphiphilic polymers taught in instant claim 71. Seo et al. do not teach

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the incorporation of the sunscreen agents listed in instant claim 75. These deficiencies are cured by the teachings of L'Alloret.

L'Alloret teaches a block copolymer comprising both water soluble block and a hydrophobic polymer block (abstract). L'Alloret teaches the incorporation of diblocks polymers A'-B comprising a neutral water-soluble polymer block A' and a hydrophobic polymer block B for synergistic action with the triblock polymers B-A-B (column 11, lines 38-41). The examiner notes that in the triblock polymers A is an ionic water soluble and B is a hydrophobic portion however in the diblock polymers A'-B, A' is a neutral water-soluble polymer block and B is a hydrophobic polymer block (column 11, lines 45-46). The neutral water-soluble block A' may be a polyoxyalkylenated and especially polyoxyethylenated or polyoxypropylenated polymer (homopolymer or copolymer) such as, for example, polyethylene oxide (PEO), polypropylene oxide (PPO), copolymers of ethylene oxide (EO) or of propylene oxide (PO) and mixtures thereof (column 11, lines 59-64). L'Alloret teaches most of the hydrophobic polymers recited in the above instant claims in examples of hydrophobic monomers (Ig) that may be mentioned include: styrene and its derivatives such as 4-butyl-styrene etc (column 13, lines 1-47) which addresses 61, 66, 68-69, and 71.

The hydrophobic portion may be made from methyl methacrylate, ethyl methacrylate, n-butyl methacrylate, tert-butyl (meth)acrylate, cyclohexyl acrylate, isoboronyl acrylate and 2-ethylhexyl acrylate, and trifluoromethyl (meth)acrylate (column 8, line 62-column 9, line 3). Water soluble monomers include (meth)acrylamide, N-vinylacetamide, N-methyl-N-vinylacetamide, N-vinylformamide, and N-methyl-N-vinylformamide (column 9, lines 46-49). Additional water soluble blocks may be polyoxyalkylenated polymers including both homo and

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copolymers (column 11, lines 59-64). Active agents which may be included in the composition are anti-inflammatory agents, vitamins DHEA and derivatives of DHEA (column 17 lines 29-50). Sunscreens which may be included in the composition are p-aminobenzoic acid derivatives, salicylic acid derivatives, dibenzoylmethane derivaives, cinnamic derivatives, denzophenone derivatives, benzylidenecamphor derivatives, phenylbenzimidazole derivatives, triazine derivatives, phenylbenzotriazole derivatives, anthranilic derivatives, imidazoin derivatives (column 18 line 34 column 20, line 23).

L'Alloret also teaches the composition also comprises active agents such as anti-inflammatory agents, vitamins etc (column 17, line 28-50), which addresses instant claim 72. L'Alloret also teaches the composition also comprises sunscreen agents such as benzophenone derivatives (column 19, lines 14-30), triazine derivatives (column 19, lines 51-57) etc, which addresses instant claim 75. L'Alloret also teaches the composition also comprises 1,3,5-triazine derivatives such as diethylhexylbutamidotriazone (column 20, line 21), which is 2-[(p-(tert-butylamido)anilino]-4,6-bis[(p-(2'-ethylhexyl-1'-oxycarbonyl)- anilino]-1,3,5-triazine, which addresses instant claim 76. L'Alloret also teaches the composition comprises organic UV screening agents that more particularly preferred and the list contains butylmethoxydibenzoylmethane (column 20, lines 6-9), which addresses instant claim 77.

***Finding of Prima Facie Obviousness Rationale and Motivation
(MPEP §2142-2143)***

It would have been prima facie obvious to modify the teachings of Seo et al. to incorporate the hydrophilic and hydrophobic polymer blocks taught by L'Alloret because both Seo et al. and L'Alloret teach compositions comprising amphiphilic block polymers and

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lipophilic compounds. The skilled artisan would have been motivated to modify the block polymers to optimize the solubility of the lipophilic compound. Alternatively, the skilled artisan could modify the polymers to optimize the composition for a particular application. The skilled artisan would have had a reasonable expectation of success because Seo et al. and L'Alloret use some of the same types of lipophilic compounds in the compositions that comprise amphiphilic block polymers.

It would have been *prima facie* obvious to modify the teachings of Seo et al. to incorporate other lipophilic compounds including the sunscreen agents because L'Alloret teach the incorporation of lipophilic compounds such as sunscreen agents. The skilled artisan would have been motivated to incorporate sunscreen agents because sunscreen agents are important for human health and the prevention of skin cancer. The skilled artisan would have had a reasonable expectation of success because Seo et al. and L'Alloret teach compositions comprising amphiphilic block copolymers and lipophilic compounds including some of the same types of lipophilic compounds.

It would have been *prima facie* obvious for the ordinary person skilled in the art at the time the invention was made to routinely optimize various weight values for the block copolymer and the lipophilic compound, since it is a routine practice performed by the skilled artisan. Moreover, based on (see MPEP 2144.05 *In re Aller*, 220 F. 2d 454, 456, 105 USPQ 233, 235 (CCPA 1955)) “differences in concentration (weight values and ratios in the case of the instant application) will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical, and also since the general conditions of the instant claim 84 are disclosed in the prior art, it is not inventive to discover the

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optimum or workable ranges by routine experimentation.” The skilled artisan would have been motivated to optimize the concentration of the lipophilic compound to maximize the effectiveness of the composition. The skilled artisan would have a reasonable expectation of success because the ranges taught in instant claim 84 overlap with the concentration range taught by Seo et al.

In light of the forgoing discussion, one of ordinary skill in the art would have concluded that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Claims 61 and 73-74 are rejected under 35 U.S.C. 103(a) as being unpatentable over Seo et al. (WO 01/12718) in view of L’Alloret (US Patent No. 6994846) and Guiramand et al. (US 2003/0027864).

Applicant Claims

The claimed subject matters of instant claims 61 and 73 are set forth above. Instant claim 74 requires the composition further comprises at least one salicylic acid derivative from the list given in the claim.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

The teachings of Seo et al. and L’Alloret are set forth above.

Ascertainment of the Difference Between Scope the Prior Art and the Claims

(MPEP §2141.012)

This differs from the claimed limitation in instant claim 74 in that Seo et al. do not teach the types of salicylic acid derivatives recited in the instant claim. These deficiencies are cured by Guiramand et al..

Guiramand et al. teach a cosmetic composition comprising salicylic acid derivatives 5-n-decanoylsalicylic, 5-n-dodecanoylsalicylic, 5-n-octylsalicylic etc (see claim 14).

Finding of Prima Facie Obviousness Rationale and Motivation

(MPEP §2142-2143)

It would have been *prima facie* obvious for the ordinary person skilled in the art at the time the invention was made to modify the composition of Seo et al. by incorporating salicylic acid derivatives selected from the list recited in the instant claim as taught by Guiramand et al., because the salicylic acid derivatives are one of the many insoluble organic compounds. The skilled artisan would have been motivated to incorporate the salicylic acid derivatives taught by Guiramand et al. because useful for repairing the main manifestations of ageing of the skin (page 5, paragraph 0092). The skilled artisan would have had a reasonable expectation of success because Seo et al. already teach the incorporation of aspirin which is one derivative of salicylic acid.

In light of the forgoing discussion, one of ordinary skill in the art would have concluded that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

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Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Claim 61, 72, and 85 is rejected under 35 U.S.C. 103(a) as being unpatentable over Seo et al. (WO 01/12718) in view of L'Alloret (US Patent No. 6994846) and Grollier et al. (US Patent No. 5246693).

Applicant Claims

The claimed subject matters of instant claim 61 and 72 are set forth above. Instant claim 85 recites the lipophilic compound is selected from essential oils selected from the list.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

The teachings of Seo et al. and L'Alloret are set forth above.

Ascertainment of the Difference Between Scope the Prior Art and the Claims

(MPEP §2141.012)

This differs from the claimed limitation in instant claim 85 in that Seo et al. do not disclose the same essential oils recited in the instant claim. These deficiencies are cured by Grollier et al..

However, Grollier et al. teach a cosmetic composition comprising essential oils selected from eucalyptus, lavandin, lavender, vetiver, litsea cubeba, lemon, sandalwood, red or white

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thyme, rosemary, camomile, savory, nutmeg, cinnamon, hyssop, caraway and orange, clove, mint, rose and parsley seeds (column 3, 21-26).

Finding of Prima Facie Obviousness Rationale and Motivation
(MPEP §2142-2143)

It would have been *prima facie* obvious for the ordinary person skilled in the art at the time the invention was made to modify the composition of Seo et al. by incorporating essential oils selected from the list recited in the instant claims, because the essential oils are also lipophilic compounds. The skilled artisan would have been motivated to include essential oils such as those taught by Grollier et al. because they are known to safely provide moisture to humans. The skilled artisan would have had a reasonable expectation of success because both Seo et al. and Grollier et al. teach compositions comprising amphiphilic compounds for enhancing solubility of poorly soluble lipophilic compounds.

In light of the forgoing discussion, one of ordinary skill in the art would have concluded that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

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Conclusion

Claims 61-66, 68-80, 84-85, and 87-88 are rejected, while claims 41-60, 81-83, and 86 are withdrawn. Claims 1-40, 53 67, and 83 are cancelled. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TIGABU KASSA whose telephone number is (571)270-5867. The examiner can normally be reached on 9 am-5 pm Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Tigabu Kassa

9/05/09

/Mina Haghighatian/

Primary Examiner, Art Unit 1616